DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vanguard Medical Concepts, Inc.
c/o Ms. Heather Crawford, RAC
Director of Regulatory Affairs
5307 Great Oak Drive
Lakeland, FL 33815

NOV 1 2004

Re: K022316 - Supplemental Validation Submission
Trade Name: Vanguard Reprocessed EPT Explorer™ 360 Diagnostic EP Catheters
Models 5291S, 5292S, 5294S, 5433S and 5461S
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: II (two)
Product Code: NLH
Dated: July 15, 2002
Received: July 17, 2002

Dear Ms. Crawford:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on October 10, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed above are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number: K022316

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022316

K022316

OCT 1 0 2002

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

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Date

July 15, 2002

Device

- Trade Names: Vanguard Reprocessed Diagnostic Electrophysiology Catheters
  ⇒ EP Technologies™ Explorer 360™ Diagnostic Electrophysiology Catheters
- Common Name: Electrode Recording Catheter, Diagnostic Electrophysiology (EP) Catheter
- Classification: 21 CFR 870.1220 – Class II – Catheter, Electrode Recording, or Probe, Electrode Recording
- Product Code DRF

Predicate Devices

EP Technologies™ Explorer 360™ diagnostic EP catheters legally marketed under various 510(k) premarket notifications.

Indications for Use

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

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510(k) Summary of Safety & Effectiveness, Continued

Contra-indications

- Patients with active systemic infection.
- Patients with prosthetic valves.
- Retrograde approach in patients with aortic valve replacement.
- Transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle patch.
- Diagnostic EP catheters are not intended for electrical ablation.

Device Description

Explorer 360™ diagnostic electrophysiology catheters are constructed of a 6 French hollow polymer shaft 100 cm in length. The quadripolar catheters are available with various fixed distal curves and electrode spacing configurations. The polymer shaft is manufactured with additives (typically barium sulfate) that enhance its radiopacity during fluoroscopic positioning of the catheter. The platinum alloy electrodes are sealed to the distal catheter and internally wired to a proximal shielded Nexus connector for bi-directional transmission of electrical signals (pacing and recording). The connector is designed to be attached to a compatible instrument cable that interfaces with various standard types of sensing, recording, stimulation, and pacing equipment.

Vanguard receives previously used diagnostic EP catheters from healthcare facilities; cleans, inspects, tests, refurbishes, applies a unique serial number, repackages, and sterilizes the devices; and returns them to the healthcare facility.

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510(k) Summary of Safety & Effectiveness, Continued

Technological Characteristics	The Vanguard reprocessed Explorer 360™ diagnostic catheters are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.
Test Data	Cleaning, sterilization, and packaging validations; and functional/ performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard Reprocessed Diagnostic EP Catheters (EP Technologies™ Explorer 360™ Catheters) are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.